UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS INTERNATIONAL PHARMACEUTICAL AG, Plaintiff, v. INCYTE CORPORATION, Defendant.	**Case No. 1:20-cv-00400-GHW** **Hon. Gregory H. Woods**

NOVARTIS INTERNATIONAL PHARMACEUTICAL AG'S MEMORANDUM OF LAW IN OPPOSITION TO INCYTE CORPORATION'S MOTION TO DISMISS

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Novartis respectfully submits its Opposition to Incyte's Motion to Dismiss (the "Motion").

SUMMARY OF ARGUMENT

This case grows out of Incyte's underpayment of royalties to Novartis in increasing magnitudes with each passing fiscal quarter under the parties' Collaboration and License Agreement dated November 24, 2009 (the "Agreement").[1] Although at the heart of the Agreement, as spelled out in various ways, is the principle of collaboration (which is featured in its very title), Incyte has hardly followed that principle by using Novartis as a lifeline to develop and commercialize a compound it discovered, but then seeking to deprive Novartis of an estimated billion dollars in royalties to accrue over the next eight years that it contractually agreed to pay.

Under the Agreement, Incyte—which had never previously brought a product to market—shared intellectual property with Novartis and provided Novartis with two exclusive licenses to Incyte IP, including its Patent Rights. In exchange, Novartis contributed necessary funding, significant technical and industry expertise from having commercialized dozens of pharmaceutical products, and a global scale of organization. As a framework for allocating responsibilities relating to ruxolitinib, the Agreement grants Incyte exclusive rights to market and sell it as a Licensed Product in the U.S., as well as rights to file, prosecute, and maintain patents protecting it. Novartis, for its part, was given rights to commercialize ruxolitinib everywhere else. The parties also agreed to pay each other royalties based on Licensed Product sales in their respective territories.

Following execution of the Agreement, Incyte and Novartis successfully brought ruxolitinib, branded as Jakafi in the U.S., to patients around the world with rare blood cancers and other rare conditions. Since Jakafi launched in the U.S. in 2011, net product revenues have

[1] Terms used herein and not otherwise defined shall be given the same meaning as in the Agreement and its amendments (the "Agr."), which is in the record. (Rec. Docs. 36 (redacted); 39 (sealed)). Incyte's Memorandum of Law in Support of its Motion (Rec. Doc. 35) is referred to herein as "Mot."

increased to over $1.7 billion in 2019, are expected to surpass $2 billion in 2020, and are projected to remain above that level for the next eight years. Currently, Jakafi is protected from competition in the U.S. because it is covered by (1) eight patents, with the last set to expire in 2028; and (2) three regulatory exclusivities granted by the U.S. Food and Drug Administration ("FDA"), with the last set to expire in 2026. Despite, however, the undeniable strength of Jakafi's long-term market position in the U.S., Incyte is attempting an end-run around the express terms of the Agreement by misapplying words to wrongfully (1) invoke a 50% royalty reduction under Section 8.3(c) of the Agreement (the "Step Down") and (2) cut short the Royalty Term by nearly a decade.

For any Licensed Product subject to the Agreement (including Jakafi), the royalty stream lasts from the date of First Commercial Sale in the country of sale until the ***last of*** three contingencies: (1) the "last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country"; (2) ten (10) full calendar years; or (3) "the expiration of Regulatory Exclusivity for such Licensed Product." However, the Step Down is triggered to reduce royalties associated with annual Net Sales in that country in the event of either (1) the absence of "a Valid Claim of Licensed Patent Rights" ***and*** "Regulatory Exclusivity" relating to the Licensed Product; ***or*** (2) the presence of Generic Competition. Although Incyte concedes, as it must, that Generic Competition does not exist, it improperly invokes the Step Down for U.S. sales of Jakafi by claiming that there is neither any applicable "Valid Claim of Licensed Patent Rights" nor is Jakafi "subject to Regulatory Exclusivity." Incyte is wrong in **both** respects.

First, a "Valid Claim of Licensed Patent Rights" exists because eight patents protect Jakafi in the U.S. Unable to ignore those patents, Incyte instead interprets "Valid Claim of Licensed Patent Rights" as limited to situations where a patent that is licensed under the Agreement not only covers the Licensed Product but applies to that product in the specific country where the sale occurs

and is patented by the non-Commercializing party. By its terms, "Licensed Patent Rights" is broader than Incyte contends, as it covers any patent licensed between the parties under the Agreement, irrespective of where the sale of a Licensed Product is made, which recognizes the fact that the parties' collaboration is global. Even if Incyte's country-specific limitation was credited (and it should ***not*** be), Incyte expressly licensed ***all*** of its ruxolitinib patents to Novartis, including as related to Jakafi in the U.S. Nor does Incyte's limitation make commercial sense because Novartis, under the Agreement, invested literally hundreds of millions of dollars to support global collaboration, yet Incyte would require Novartis to itself invent new intellectual property, obtain a patent in the U.S., and license it to Incyte in the U.S. where that patent benefits Incyte's Commercialization of Jakafi, in order for Novartis to continue to receive 5% in royalties on U.S. sales—which is not consistent with the financial allocation of rights and responsibilities for the 5% royalty. To artificially restrict the meaning of "Valid Claim of Licensed Patent Rights," as Incyte seeks to do, to an unreasonable situation for Novartis would, as a practical matter, eviscerate Novartis' return on its investment by nullifying the use of the term in Section 8.3(c) as (1) a possible endpoint for determining the duration of the Royalty Term for Jakafi U.S. sales and (2) a basis for avoiding the Step Down for those sales. At the same time, Incyte's reading would illogically skew in its favor a longer Royalty Term for ex-U.S. sales with no Step Down.

Second, "Regulatory Exclusivity" exists because three regulatory exclusivities, including two separate orphan drug designations, cover Jakafi's treatment of polycythemia vera ("PV") and steroid-refractory acute graft-versus-host disease ("GVHD") in the U.S. Even so, Incyte attempts to justify the Step Down by relying upon the November 2018 expiration of the orphan drug designation relating to myelofibrosis ("MF"), the third condition for which Jakafi is indicated. Incyte's reliance on the expiration of a single designation is misplaced, both because royalty

payments are tied to the Licensed Product (not to any one indication or condition) and because the Licensed Product remains subject to exclusivities for the treatment of two significant medical conditions. No basis exists to pretend away these exclusivities that Incyte itself sought from FDA.

Further, "Regulatory Exclusivity" is defined as the ability to exclude other companies from "Commercializing" ruxolitinib, which, in turn, is broadly defined to encompass "any" efforts directed at marketing or selling a drug (as opposed to "all," which the parties use in different contexts elsewhere in the Agreement). Here, the Regulatory Exclusivity still in effect for two of three conditions—which, again, cannot be pretended away—satisfies that definition, since other companies are precluded from marketing or selling ruxolitinib to treat those two conditions in the U.S. This remains the case even if not all (as distinct from "any") Commercialization is prohibited.

Even aside from precise wording, basic commercial logic further belies Incyte's reading of the Agreement. As structured, Section 8.3(c) expressly ties the duration and rate of royalties to the Licensed Product enjoying a protected position, because of patents and/or exclusivities, to generate high margins. Thus, Generic Competition is a basis for the Step Down as it obviously depresses margins. If, on the flip side, no patents or exclusivities preclude Generic Competition but such competition still has not emerged, it likewise is clear that margins are then unattractive or competition otherwise would enter. As Jakafi sales continue to soar in the U.S., with no detrimental change to Incyte's protected market position, it would be illogical given what Incyte vaguely calls the "business deal memorialized in the Agreement," Mot. at 2, to trigger the Step Down or curtail the Royalty Term in these circumstances.

Although Novartis' interpretation of Section 8.3(c), as pled in the Complaint, is facially correct, the Court need not resolve the question of which party's reading is right on the Motion. Rather, Incyte has the burden to show that Novartis fails to even offer "a ***plausible*** interpretation."

Dresser-Rand Co. v. Ingersoll Rand Co., No. 18-cv-3225, 2019 WL 1434575, at *5-6 (S.D.N.Y. Mar. 29, 2019). As Novartis so clearly does at least that, Incyte's Motion should be denied.

FACTUAL BACKGROUND AS PLED IN NOVARTIS' COMPLAINT

Global Collaboration Under the Agreement

Prior to entering into the Agreement, Incyte did not sell or market any drug but had "discovered and commenced Development of the Licensed Compounds." Agr. at 1; Compl. ¶ 1. Incyte recognized that it could not effectively develop and commercialize these compounds on its own, prompting its collaboration with Novartis. *Id.* In exchange for being granted "the right to develop and commercialize" these compounds, Novartis agreed to contribute necessary funding, technical and industry expertise, and a global scale of organization. Agr. at 1; Compl. ¶¶ 1, 14. As for funding, Novartis agreed to pay $150 million upfront, [redacted] of the costs associated with development activities and clinical trials, [redacted] milestone payments in various forms, and royalties. Compl. ¶ 14; Agr. at 33-34 (§4.3(a)) and 51-56 (§§8.1-8.3(a)). Novartis' contributions permitted the parties to Commercialize ruxolitinib, which treats two rare blood cancers and a condition that occurs after an allogenic tissue transplant (where donor cells attack host organs and/or tissue). Compl. ¶¶ 23-24. In addition, the parties allocated responsibility for the marketing and sale of Licensed Products covered by the Agreement, with the U.S. sales of ruxolitinib allocated to Incyte and all ex-U.S. sales allocated to Novartis. Compl. ¶¶ 2-3, 14-15.

Incyte's Patents and the Prosecution and Maintenance of Patent Rights Under the Agreement

Prior to execution, Incyte had already filed a variety of patent applications relating to its discovered compounds, including patent applications in the U.S. pertaining to ruxolitinib. Agr. at Ex. A-2. The compound patent applications Incyte filed relating to ruxolitinib were categorized as the "INCY0039" group. *Id.* at 15 (§ 1.107) and Ex. A-2. As the inventor of ruxolitinib, Incyte expressly reserved the rights to file, prosecute, and maintain the INCY0039 Patent Rights

worldwide, as well as sole rights to file, prosecute, and maintain Secondary JAK Patent Rights in the [redacted] *Id.* at 47 (§ 7.2(c)). Novartis was left, at most, with a remote ability—which is nowhere even explicitly contemplated within the Agreement—to invent, on its own, something new pertaining to ruxolitinib and obtain U.S. patent protection for it. *See id.* at 46 (§7.2(a)).

Licenses Granted Under the Agreement

As part of their collaboration, both sides issued licenses under the Agreement. Agr. at 18-19 (§§ 2.1-2.2). Incyte's exclusive licenses granted to Novartis were issued "under Incyte IP." *Id.* at 18 (§ 2.1). "Incyte IP" is expressly defined as "Incyte Know-How and Incyte Patent Rights," which are in turn defined to include "all Know How" and "all Patent Rights" controlled by Incyte that are "necessary or useful to Develop, manufacture or Commercialize." *Id.* at 8 (§§ 1.45–1.47).[2]

Known as the JAK License, one of two licenses granted by Incyte to Novartis covers ruxolitinib (Jakafi in the U.S.). *Id.* at 18 (§ 2.1(b)). Although the JAK License excludes Commercialization and sales in the U.S.—consistent with the sales territory allocation in the Agreement, as those are Incyte-only activities—it explicitly grants a number of other important rights to Novartis in the U.S. *See* Compl. ¶¶ 2, 14-16; Agr. at 18 (§ 2.1(b)).[3] Thus, Incyte Patent Rights licensed to Novartis under the JAK License necessarily includes ***all*** patents associated with ruxolitinib—including those U.S. patents covering ruxolitinib as it is marketed and sold by Incyte in the U.S. (as Jakafi)—provided that Novartis is not using those rights to attempt to market and sell ruxolitinib in Incyte's territory (which it is not).

[2] "Patent Rights," in turn, is broadly defined to include "all patents and patent applications in any country in the world," without restriction or time limitation, and the definition enumerates examples of subsequent submissions relating to patent applications or patents that would be included within this all-encompassing term. *Id.* at 13 (§ 1.86).
[3] Pursuant to the JAK License, Incyte granted Novartis a license to "research, Develop, make and have made JAK Licensed Compounds and JAK Licensed Products in the Incyte Territory [(*i.e.*, the U.S.)] for the sole purpose of using, offering for sale and selling JAK Licensed Products in, and importing JAK Licensed Compounds and JAK Licensed Products into, the Novartis JAK Territory in the JAK Field [(*i.e.*, in all other countries in the world)]." *Id.*

Incyte's Patent Rights in the U.S. and Other Patent Rights Covering Ruxolitinib

After the Agreement was executed, Incyte pursued additional patent applications relating to ruxolitinib across the globe, including in the U.S., securing altogether eight U.S. patents that cover all three approved indications for Jakafi (including the compound patent it had previously applied for and which was listed on Exhibit A-2 to the Agreement). Compl. ¶¶ 25-26. The latest expiration date for these patents, all of which were licensed to Novartis under the JAK License, is in 2028. *Id.*

FDA-Approved Indications and Incyte's Regulatory Exclusivities in the U.S.

Approximately two years after the Agreement was made effective, on November 16, 2011, Incyte received approval from FDA for the MF indication as well as a corresponding 7-year orphan drug exclusivity. *Id.* ¶¶ 6, 23, 29. Incyte's First Commercial Sale of Jakafi followed in late 2011. *Id.* ¶ 31. Incyte subsequently obtained an FDA-approved indication for PV on December 4, 2014, and a third FDA-approved indication for GVHD on May 24, 2019. *Id.* ¶ 24. The FDA's approvals of these indications were accompanied by orphan drug status, and GVHD was also provided a 3-year New Clinical Investigation ("NCI") exclusivity. *Id.* ¶¶ 24, 28. The development activities and clinical trials that supported the applications to FDA were the result of collaboration, with Novartis both paying for [redacted] and providing expertise. Agr. at 33-34 (§4.3(a)).

FDA's regulations provide that once a sponsor obtains orphan drug status with respect to its drug to treat a rare disease or condition, any subsequent person seeking FDA approval to market the same drug for the same disease or condition will be prevented from doing so for 7 years. *See* 21 C.F.R. § 316.3(b)(12); 21 C.F.R. § 316.31. This effectively grants a drug company a statutory exclusivity period of 7 years during which it can market and sell their product to treat a specific condition without the prospect of competition. Incyte's orphan drug exclusivity for MF expired on November 16, 2018. Compl. ¶¶ 23, 29. However, its orphan drug exclusivities for PV and GVHD remain valid, expiring in 2021 and 2026, respectively. *Id.* ¶¶ 24, 28, 30.

The Agreement's Bilateral Royalty Provision

The parties also agreed to pay each other royalties based on drug sales in their respective territories (*i.e.*, Incyte in the U.S. and Novartis elsewhere). *Id.* ¶ 2. While the royalty rates to be paid differ (with Incyte paying significantly lower rates than Novartis pays), the parameters applying to the payment of royalties based on product sales in any country, including the length of time royalties are to be paid and the limited circumstances under which a 50% reduction is triggered pursuant to the Step Down, are bilateral. *See id.* ¶¶ 14-17.

Section 8.3(c) of the Agreement states that royalties shall be paid by Incyte or Novartis, as applicable, on a per-product and per-country basis from the date of First Commercial Sale of a drug in that country until one of three possible endpoints, whichever results in "a period which is the ***longer***" Royalty Term. Compl. ¶¶ 5, 17; Agr. at 57 (§ 8.3(c)) (emphasis added). By selecting the "longer" of the endpoints, this structure incentivizes and recognizes collaboration across all sales territories. *See id.* The three endpoints are (i) the "last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country"; (ii) "ten (10) years following the date of First Commercial Sale in such country," ***or*** (iii) "the expiration of Regulatory Exclusivity for such Licensed Product in such country." Compl. ¶¶ 5, 17; Agr. at 57 (§ 8.3(c)).

Section 8.3(c) also includes the Step Down, which provides for a 50% reduction in royalties if the Royalty Term only exists pursuant to endpoint (ii), *i.e.*, the minimum 10-year period. *Id.* In that case, the drug is less valuable either because it faces Generic Competition or it has no patent or exclusivity protections (but Generic Competition does not exist presumably due to unattractive margins). *See* Compl. ¶¶ 5-6, 19-20. In pertinent part, the Step Down provides:

> . . . in the event that ***either*** (A) the Royalty Term continues solely due to clause (ii) (i.e. in a specific country the Licensed Product is neither Covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity) ***or*** (B) Generic Competition exists with respect to a Licensed Product in a country with respect to a royalty-reporting

> period, then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be reduced to fifty percent (50%) of the applicable rate in Section 8.3(a) or 8.3(b) . . .

Compl. ¶ 18; Agr. at 57 (§ 8.3(c)) (emphasis added).

Thus, the Step Down can be invoked by the payor (1) if there is no barrier to entry to the market for a hypothetical competitor, ***or*** (2) if at least one generic competitor has already entered the market and the royalty payor has lost at least [redacted] of the market share for the drug. *See* Agr. at 7-8 (§ 1.40) and 57 (§ 8.3(c)). As it must, Incyte concedes the second possible scenario to trigger the Step Down, involving Generic Competition, has not occurred here. *See* Mot. at 8. Only the first possible scenario is at issue with respect to Incyte's sales of Jakafi in the U.S.

As Jakafi Sales Soar, Incyte Improperly Invokes the Step Down

Incyte's sales of Jakafi have increased dramatically since Jakafi was first approved back in late 2011. Compl. ¶ 33. Incyte reported $2,012,000 in net product revenues to the U.S. Securities & Exchange Commission ("SEC") for the 2011 fiscal year. *Id*. Comparatively, Incyte reported in its annual 10-K filing that it had approximately $1.4 billion in net product revenues for Jakafi alone in 2018 and $1.7 billion in net product revenues for Jakafi in 2019.[4] Incyte also reported to its investors at the time of issuing its 2019 fiscal year results that it projected nearly $2 billion in net product revenues for Jakafi for the 2020 fiscal year. Incyte's May 5, 2020 press release, reporting on the first quarter of 2020, has advised that its net product sales for Jakafi have gone up 22% as compared to the first quarter of 2019. Since the loss of the MF orphan drug designation in November 2018, Incyte's net product revenues (as reported to the SEC) and Net Sales (as reflected

[4] In ruling on the Motion, pursuant to Fed. R. Evid. 201, this Court may consider documents publicly filed with the SEC, government agency websites, and information publicly announced such as on a party's own website. *E.g., In re American Int'l Grp., Inc, 2008 Sec. Litig.*, 741 F. Supp. 2d 511, 519, 529 (S.D.N.Y. 2010) (taking judicial notice of "public filings" such as SEC disclosures). The sales figures and data referenced herein are based on Incyte's 10-K for the 2019 fiscal year and May 5, 2020 and February 13, 2020 press releases, all of which are publicly available on Incyte's website. *See* Incyte, For Investors, https://investor.incyte.com/investor-relations (last visited May 18, 2020).

in its royalty reporting to Novartis) have only continued to rise substantially.[5]

Approximately two fiscal quarters after the loss of the MF orphan drug designation, Incyte unilaterally applied, with sales escalating, the Step Down to its royalty payments owed to Novartis, cutting the amount in half. Compl. ¶¶ 37-38. Novartis promptly disputed Incyte's Step Down interpretation, leading eventually to this litigation. *Id.* ¶¶ 39, 45-47.

ARGUMENT[6]

As Courts in this District repeatedly have held, the "only task before the Court" in considering a Fed. R. Civ. P. 12(b)(6) motion predicated on a defendant's competing contractual interpretation is to determine whether the plaintiff "state[s] a ***plausible*** claim" that "its interpretation of the contract is the correct one." *Columbia Cas. Co. v. Neighborhood Risk Mgmt. Corp.*, No. 14-cv-0048, 2015 WL 3999192, at *9 (S.D.N.Y. June 29, 2015) (emphasis added); *see also Dresser-Rand*, 2019 WL 143575, at *5 (denying motion to dismiss because plaintiff "offer[ed] a ***plausible*** interpretation, based upon the contract's operative provisions"); *Clarendon Nat'l Ins. Co. v. Health Plan Adm'rs*, No. 08-cv-6279, 2009 WL 3053736, at *3 (S.D.N.Y. Sept. 24, 2009) (denying motion to dismiss contract claim where the parties "draw different conclusions as to the specific duties the agreements impose").

Although the plain language of the Agreement, on its face, confirms the inapplicability of the Step Down in the present circumstances, Novartis at this stage only needs to set forth a "plausible" contract interpretation, which it more than amply does. Put differently, this Court "need ***not*** decide the correct interpretation of [the Agreement] at this stage." *Columbia Cas. Co.*,

[5] Although Incyte as a distraction references Novartis' profits, *see* Mot. at 10, Novartis has consistently paid royalty payments for ex-U.S. sales to Incyte. Compl. ¶ 3. Indeed, it does so at a significantly higher royalty rate than Incyte pays Novartis. The issue, however, is not about generating profits, but about the contradiction between increasing revenues and Incyte's claim of a Step Down in these favorable circumstances in violation of its contractual obligations.
[6] The parties agree that the Agreement is to be construed under New York law. *See* Mot. at 13; Agr. at 75-76 (§14.1).

2015 WL 3999192, at *9 (emphasis added). Nor does the limited issue before the Court on the Motion change simply because each side claims that the Agreement is unambiguous in its favor. *See, e.g.*, *Citibank, N.A. v. Jacobsen,* No. 19-cv-959, 2020 WL 1503229, at *7 (S.D.N.Y. Mar. 30, 2020) (denying motion to dismiss breach of contract claim, noting that "[t]he Court need not decide now as between whether the term is ambiguous or unambiguous in its inclusion of the loan repayment obligation"); *see also American Bldg. Maint. Co. of N.Y. v. Acme Prop. Servs., Inc. et al.*, 515 F. Supp. 2d 298, 311 (N.D.N.Y. Aug. 29, 2007) (denying motion to dismiss breach of contract claim because the parties' "conflicting interpretations [of the contract] mean that ABM is entitled to present evidence to the fact finder regarding the parties' intentions").

As a red herring, Incyte seeks to bolster its position by citing the Agreement's integration clause. Mot. at 9. But that clause is of no moment because Novartis does not seek to "add to or vary" contract terms, although the same cannot be said of Incyte.[7] Despite paying lip service to "the four corners of the Agreement," Mot. at 5, Incyte seeks to vary terms by resorting to disputed assertions about hypothetical scenarios, implicit understandings, and purported extrinsic circumstances, and thus cannot carry its burden on this Motion. Incyte's repeated references to the purported "tenor and quantum" of royalties owed (whatever that means), Mot. at 1, 8, 13-16, is not enough, either.

Here, the allegations in the Complaint are accepted as true and "any contractual ambiguities" are resolved in Novartis' favor. *Int'l Business Machs. Corp. v. Smadi*, No. 14-cv-4694, 2015 WL 862212, at *4 (S.D.N.Y. Mar. 2, 2015) (citation omitted) (finding "recovery

[7] *See, e.g.*, *Matter of Primex Int'l Corp. v. Wal-Mart Stores*, 89 N.Y.2d 594, 599-601 (1997) (integration clause will bar extrinsic evidence under parol evidence rule only if it has the effect of "vary]ing] or contradict[ing] the terms of the writing"); *Telemundo Grp., Inc. v. Alden Press, Inc.*, 181 A.D.2d 453, 455 (1st Dep't 1992) ("Extrinsic or parol evidence is admissible notwithstanding such a clause where it would not modify or contradict the terms of the contract, but would explain ambiguities in the contract") (citation and internal quotation marks omitted).

cannot be limited by defendant's interpretation at this early stage"). Against this standard, there can be no serious question that Novartis' interpretation more than satisfies the plausibility standard set forth in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). While Novartis is highly confident in the merits of its positions, as pled in the Complaint, the parties' sharp differences as to the interpretation of a complex contract, coupled with the magnitude of royalties at stake, make this case appropriate for further development.

I. NOVARTIS SUFFICIENTLY PLEADS A "VALID CLAIM OF LICENSED PATENT RIGHTS" TO PRECLUDE THE STEP DOWN

A. "Licensed Patent Rights" Encompasses All Patents Covering Jakafi

The Agreement is clear that if "any Valid Claim of Licensed Patent Rights" covers the Licensed Product sold in a particular country, the Step Down does not apply. *See* Agr. at 57 (§8.3(c)(i)). As Jakafi is subject to the protection of eight valid U.S. patents owned by Incyte, *see* Compl. ¶ 26 and Mot. at 13, no basis exists to invoke the Step Down as to the U.S. sales of Jakafi.

As defined, "Licensed Patent Rights" broadly encompasses ***both*** "Patent Rights licensed to Novartis hereunder" and "Patent Rights Licensed to Incyte hereunder." Agr. at 10 (§ 1.67). The term thus broadly includes all Patent Rights, irrespective of which party to the Agreement owns an underlying patent and which party is granted a license to it. Given that, as Incyte notes, *see* Mot. at 15, "Licensed Patent Rights" is only used in Section 8.3(c), it necessarily encompasses all Patent Rights licensed by either party to the other because the Agreement's royalty provision applies bilaterally to royalties payable by ***either*** side ***for any product*** commercialized under the Agreement in ***any country***. *See* Agr. at 10 (§ 1.67) and 57 (§8.3(c)(i)); Compl. ¶¶ 17, 19.

Despite the broadly-worded scope of "Licensed Patent Rights," Incyte contends that, as used in Section 8.3(c)(i), the term is limited to circumstances where the Patent Rights are licensed under the Agreement for use in the country by the seller where the sales of a Licensed Product

occur. Even if Incyte were correct as to the status of Patent Rights being licensed in the U.S. (it is **not**, as explained below), Incyte's overly narrow construction still fails for several reasons.

First, Incyte's interpretation of "Valid Claim of Licensed Patent Rights" impermissibly adds additional limitations into Section 8.3(c) that are not set forth in the Agreement. Incyte misconstrues the wording in Section 8.3(c)(i) to mean that the Licensed Patent Rights must be licensed in the country where the sale of a Licensed Product occurs, and thus licensed to the party allocated the responsibility of Commercializing that Licensed Product in that country. *See* Mot. at 2-3, 15-16. But that is not what the royalty provision says. The phrase "in such country" relates to the geographical region of where a Licensed Product is being sold, not the geographic scope of a license being granted under the Agreement. The Agreement ***does not*** say, as Incyte contends, that the Licensed Patent Rights must be held by the non-selling party, that they must be licensed to the seller party, and that they must cover the Licensed Product sales in a particular country. If the Licensed Product (*i.e.*, the drug being sold) is protected from competition by Licensed Patent Rights (*i.e.*, the Patent Rights subject of the Agreement and licensed by the parties to one another), then a "Valid Claim of Licensed Patent Rights" exists irrespective of whether the rights are licensed to the seller in the place of sale or not—reflecting the global collaboration between the parties, since Novartis' funding and expertise aided Commercialization of ruxolitinib broadly.

Second, the structure of Section 8.3(c) refutes Incyte's narrow reading. Notably, the word "any" modifies "Valid Claim of Licensed Patent Rights" to confirm that "any" Patent Rights licensed under the Agreement, including if licensed outside of the geography of sale, satisfies the meaning of the term. *See also infra* at Part II(C) (describing plain meaning of "any" and the use of that word in the Agreement). Further, Section 8.3(c) more generally sets forth a mutual framework to maximize royalties within certain parameters—which acknowledges both sides'

material albeit different contributions as part of global collaboration and Commercialization—by linking the duration of the Royalty Term to the "period which is the longer of" three endpoints.

Third, Incyte's argument is belied by the commercial logic of the Agreement. *See, e.g.*, *Columbia Cas. Co.*, 2015 WL 3999192 at *7-8 (highlighting that business purpose(s) and "the context of the whole contract" must be considered in evaluating competing contractual interpretations). The rights constituting "Licensed Patent Rights" effectively prevent competition with the Licensed Product in any country where those rights apply. In the absence of competition in that country, the parties agreed in Section 8.3(c) to maintain royalties at non-discounted rates since both sides contributed, albeit in different ways, to achieving that enviable market position. So long as valid patents subject to the Agreement are protecting Licensed Product sales in any country, it is irrelevant whether those patents are being licensed in that country to the other party.

Had the parties meant to impose a requirement that "any Valid Claim of Licensed Patent Rights" only covers the situation where the seller of the drug in a country is the licensee of Patent Rights covering that drug, the provision could and would have clearly said so—but it does not.

B. The JAK License Provides For "Licensed Patent Rights" in the U.S.

As to Jakafi, Incyte contends that no "Valid Claim of Licensed Patent Rights" exists because purported "directionality" in that defined term requires that patents be licensed in the U.S. (which is **not** what the term says). *See* Mot. at 15-16. Even assuming Incyte's premise, Incyte's argument still fails because the JAK License covering Jakafi expressly licenses Patent Rights in the U.S. to Novartis. Despite what Incyte tries to read in, nothing in the definition of "Licensed Patent Rights" turns on whether the seller of a Licensed Product in a particular country is the licensor or the licensee with respect to any applicable Patent Rights.

Under the JAK License, ***all*** Incyte Patent Rights were licensed to Novartis globally. Agr. at 18 (§ 2.1(b)). With respect to the U.S. specifically, Novartis obtained an exclusive license

"under Incyte IP" (and necessarily to Incyte Patent Rights) to "research, Develop, make and have made" ruxolitinib and its corresponding compounds in the U.S. to use, market, import, and ultimately sell them elsewhere. *Id.* This broad license for U.S. Patent Rights makes sense within the framework of the Agreement, as Novartis retained the ability to undertake research, development, manufacturing and certain other tasks in furtherance of collaboration globally and its ex-U.S. Commercialization, even if the U.S. was not its allocated sales territory for ruxolitinib.

Incyte's characterization of the JAK License as a "limited license," *see* Mot. at 16 n.8, does not change the fact that Novartis has Licensed Patent Rights for Jakafi in the U.S. Incyte cannot ignore the U.S. component of the JAK License to contend that no "Licensed Patent Rights" exist in the U.S. for purposes of Section 8.3(c) royalties.

C. Incyte's Country-Specific Limitation Defies Commercial Logic

In a further stretch to apply the Step Down, Incyte contends that the only "Licensed Patent Rights" to consider are "Novartis Patent Rights that would have benefited Incyte in the Incyte Territory." Mot. at 16; *see also id.* at 13 ("Incyte patents are irrelevant"). To qualify, Incyte claims that Novartis should have obtained U.S. patent rights for ruxolitinib but "failed to do so." *Id.* at 16. Incyte's interpretation makes no commercial sense, particularly in context of the Agreement's framework of global collaboration and financial compensation agreed upon by each party.

Under Section 7.2 of the Agreement, [redacted] as a practical matter controls all patent activity relating to Jakafi in the [redacted] Having, as it notes, "discovered and developed" ruxolitinib, *see* Mot. at 1, Incyte is the inventor party with "the right to exclude others from making, using, offering for sale, selling or importing the invention."[8] It is for this reason that [redacted] reserved rights for itself

[8] U.S. Patent and Trademark Office ("U.S. P.T.O"), General Information Concerning Patents, *available at* https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-1 (last visited May 18, 2020) (patents are to be sought by the inventor or its assignee for something "new" and not yet patented).

under Section 7.2 with respect to patent filing, prosecution, and maintenance of critical compound patents (INCY0039 Patent Rights) worldwide as well as Secondary JAK Patent Rights in the [redacted] *See supra* at 5-7; Agr. at 18 (§2.1 (b)), 46-47 (§ 7.2(c)). Thus, it is unclear what type of ruxolitinib-related invention Incyte contends Novartis could or should have obtained for Incyte's benefit in the U.S. [9] Ignoring the allocation of responsibilities and clear-cut economics, Incyte's premise is that Novartis should have alone invented something new pertinent to Jakafi in the U.S., patented it in the U.S., and then licensed that patent to Incyte—even though Novartis would have undertaken all the burden and then only realize, at most, the 5% royalty from those U.S. sales.[10]

Nor does Incyte's interpretation credit the substantial role Novartis played in the development and ultimate Commercialization of Jakafi in the U.S., ranging from Novartis' expertise to its significant financial contributions to benefit U.S. sales (including but not limited to a significant upfront payment of $150 million and [redacted] of costs over time for Joint Development Activities). *See supra* at 5-8; Agr. at 33-34 (§4.3(a)) and 51-56 (§§8.1-8.3(b)).

Even more illogical when put in context, Incyte's interpretation skews the meaning of "Licensed Patents Rights" in the bilateral royalty provision to extend, as a practical matter, the endpoint for the Royalty Term in every country where Incyte obtains royalties, but not in the U.S. where Novartis receives royalties. That is because, under Incyte's interpretation, a "Valid Claim of Licensed Patents Rights" for ruxolitinib would exist within any ex-U.S. country where Novartis sells the drug and Incyte has obtained patents abroad as the innovator, whether those were pursued

[9] While Novartis previously explored (but did not complete) projects relating to compounds subject of the Agreement, all of them would have involved a **different** Licensed Product and thus a **separate** royalty stream.

[10] The speciousness of Incyte's argument that Novartis, to avoid the Step Down, should have obtained additional patent protection in the U.S. is further revealed when compared to Incyte's position with respect to "Regulatory Exclusivity." As to that prong of Section 8.3(c), Incyte acknowledges (as it must) that "Regulatory Exclusivity" existed in the U.S. even though Incyte sought and obtained such status from the FDA. Likewise, it does not matter which party obtained the Licensed Patent Rights for purposes of Section 8.3(c).

prior to the Agreement (and identified on Exhibit A-2 thereto) or thereafter (pursuant to Section 7.2(c)), and licensed them to Novartis. Conversely, there could rarely, if ever, be such a claim in the major U.S. market where Incyte owns all Patent Rights. By extension, Incyte's reading renders the phrase "Valid Claim of Licensed Patent Rights" in Section 8.3, as applied to Jakafi in the U.S., essentially meaningless both as to (1) a viable endpoint for the applicable Royalty Term for Incyte's royalties and (2) a viable factor for precluding the Step Down. *See, e.g.*, *Citibank,* 2020 WL 1503229 at *7 (finding "Defendants' interpretation is strained, at best," would "seem to lead to an absurd result," and "renders illogical and superfluous" contract references). Neither aspect to Incyte's one-sided, commercially unreasonable view has any merit, and it runs counter to the purpose of the bilateral royalty provision—*i.e.*, to ensure that ***both*** parties receive appropriate, long-term return on their respective contributions in bringing ruxolitinib to market globally.

II. NOVARTIS SUFFICIENTLY PLEADS THAT JAKAFI IS STILL "SUBJECT TO REGULATORY EXCLUSIVITY" TO PRECLUDE THE STEP DOWN

A. Remaining Exclusivities Exist for Two Significant Medical Conditions

Even aside from the continuing protection from eight patents covering Jakafi in the U.S.—which standing alone prevent Incyte's invocation of the Step Down—Jakafi is also "subject to Regulatory Exclusivity" in the U.S. Incyte currently holds FDA-issued orphan drug exclusivity designations for two medical conditions for Jakafi (PV and GVHD) and NCI exclusivity for GVHD. *See* Compl. ¶¶ 24, 28, 30; Mot. at 17. In fact, Incyte will hold one FDA-issued orphan drug exclusivity designation relating to Jakafi through 2026. *Id.* Given these undeniable facts, Incyte has no basis to invoke the Step Down even with the expiration of the MF designation.

B. Royalties Pertain to Licensed Products, Not Indications or Medical Conditions

By its terms, the bilateral royalty provision and Step Down tie royalties to the entire drug and not to the individual indications or conditions for which it was prescribed. This is so even

though the parties expressly recognized the prospect of receiving multiple approved indications in the Agreement and tied other payments (but ***not*** royalties) to indications. Nor did the parties agree anywhere in the Agreement that the loss of one regulatory exclusivity for one medical condition would amount to the loss of all Regulatory Exclusivity for the entire drug product. No basis exists for Incyte to read such an unstated provision into the Agreement, which was not bargained for.

As the Agreement makes clear, the parties expressly contemplated the prospect of obtaining approval for multiple indications for any Licensed Product (and corresponding regulatory exclusivities), including ruxolitinib. *See* Compl. ¶ 21.[11] In particular, Article VIII requires Novartis to provide payments to Incyte based on multiple categories of "milestone events" with the timing and size of the payments given based on the number of indications. *See* Agr. at 51-56 (§ 8.2). Put differently, Incyte contemplated (and has reaped) milestone payments premised on the shared goal of extensively commercializing the compounds covered by the Agreement and seeking multiple approved indications for ruxolitinib. The bilateral royalty provision in Article VIII, however, does not follow the same or even a similar structure. *See* Agr. at 56-57 (§ 8.3).

Had the loss of ***one*** regulatory exclusivity—such as an orphan drug designation, which is specifically enumerated in the definition of Regulatory Exclusivity—amounted to the loss of ***all*** Regulatory Exclusivity, this would have been stated in Section 8.3, but it was not. *See* Agr. at 15 (§ 1.101) and 57 (§ 8.3(c)). As reflected by the immediately-preceding Section 8.2, the parties knew how to draw distinctions based on indications for a drug but did not do so in Section 8.3. Ignoring the fact that Section 8.2 uses different wording to set forth an indication-oriented structure, Incyte argues that, without textual support, the loss of Regularly Exclusivity under Section 8.3 for only one medical condition means a loss of Regulatory Exclusivity for the entire

[11] This is reflected by Incyte's track record vis-à-vis the FDA, as each application for an additional indication/approved use has been coupled with a request for regulatory exclusivities. *See* Compl. ¶¶ 23-24; Mot. at 9, 17.

Licensed Product even though other valid and applicable forms of Regulatory Exclusivity exist for other medical conditions. Incyte also goes so far as to suggest that the ongoing existence of multiple "exclusivit***ies***" somehow falls outside the scope of "Regulatory Exclusivity," irrespective of the number of medical conditions with approved FDA indications that remain subject to exclusivity. *See* Mot. at 17-18. That interpretation, however, is belied by the distinct language used in various sections of the Agreement, as well as commercial logic. *See Jones v. Mercedes-Benz, Manhattan, Inc.*, No. 1:19-cv-00472, 2020 WL 1445728, at *6 (S.D.N.Y. Mar. 25, 2020) (denying motion to dismiss contract claim because defendants' interpretation disregards the import of having two distinct and "separate sections for salary and commissions" and the "specific way in which commissions, as opposed to salary were earned").

C. Existing Exclusivities Preclude Commercialization Activities for Jakafi

As defined in the Agreement, the term "Regulatory Exclusivity" means the ability to exclude other companies from "Commercializing" a Licensed Product in a manner different from Patent Rights. Agr. at 15 (§1.101) and 5 (§1.19). Not using the words "all" or "every," the definition of "Commercialization" is instead "**any** activities directed to obtaining pricing and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling a product (including establishing the price for such product)," *id.* at 5 (§ 1.19) (emphasis added), such that one, or some, activity is enough. It follows that "Regulatory Exclusivity" means an ability, granted by a regulatory authority (*e.g.*, FDA in the U.S.), to prevent non-collaborators from partaking in at least one, or some, activities—irrespective of the total number or type—geared towards selling a Licensed Product and competing in the relevant market. Incyte's remaining designations for two conditions, which are substantial sales drivers, clearly meet that standard.

The use of the word "any" in Section 1.19 of the Agreement thus has significance. In fact, the word "any" is employed repeatedly throughout the Agreement to connote the equivalent of "at

least one" within a potential class or group where there is an unknown potential quantity of such things within the class or group.[12] This is in sharp contrast to the parties' use of the word "all" in the Agreement to connote all-encompassing inclusion.[13] The use of the modifier adjectives "any" and "all" separately shows that the parties knew how to draw clear distinctions, depending on context, with "any" being used to modify nouns to reflect that there may be one or more things that may qualify to fall within the scope of the term (*e.g.*, in defining "Indication") and "all" being used to modify nouns to reflect that the whole number or sum of those things was to be included in the term (*e.g.*, in defining "Patent Rights"). This interpretation gives "reasonable meaning" to all of the Agreement's language and provides a "consistent" reading of its adjectives throughout, while at the same time does not render the clear distinction between "any" and "all" meaningless.[14]

Were there to be any doubt as to the meaning of the word "any" in Section 1.19, New York precedent refers to dictionaries to aid in determining plain and ordinary meaning.[15] Although Incyte resorts to dictionary definitions, *see* Mot. at 20, it does not fairly capture what they say.

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[12] For example, "Indication" is "**any** disease, condition or syndrome, or sign or symptom of, or associated with, a disease or condition." *Id.* at 8 (§ 1.50). Similarly, "Generic Product" is "**any** pharmaceutical product that contains a Licensed Compound and that is sold under a marketing authorization granted by a Regulatory Authority to a Person other than a Party or its Affiliates, licenses, or sublicensees." *Id.* at 8 (§ 1.41). *See also id.* at 9 (§ 1.51), 10 (§ 1.64), and 14 (§ 1.96) (defining "Inflammatory Disease," "Know-How," and "Publication," respectively).

[13] By way of example, "Patent Rights" is defined as "**all** patents and patent applications in any country in the world . . ." and "Incyte Patent Rights" is defined as "**all** Patent Rights that (a) are Controlled by Incyte or any of its Affiliates as of the Effective Date or during the Term; and (b) are necessary or useful to Develop, manufacture or Commercialize . . ." Agr. at 13 (§1.86) and 8 (§1.47).

[14] *See, e.g.*, *Serdarevic v. Centex Homes, LLC*, 760 F. Supp. 2d 322, 333 (S.D.N.Y. 2010), 760 F. Supp. 2d at 333 (denying motion to dismiss contract claim as defendant's interpretation would make a phrase "meaningless" and plaintiff's would not, noting "the Court need not decide this issue as a matter of law" now); *Air China Ltd. v. Li*, No. 07-cv-11128, 2008 WL 754450, at *2 (S.D.N.Y. Mar. 17, 2008) (rejecting interpretation "render[ing] [another provision's instruction] . . . meaningless and, more generally, is nonsensical"); *Kohl's Dep't Stores, Inc. v. Rongrant Assocs. LLC*, No. 04-cv-4907, 2005 WL 1263613, at *3 (E.D.N.Y. May 27, 2005) (denying motion to dismiss where plaintiff's interpretation is "consistent with the text of the Lease and gives meaning to each subsection of Section 9").

[15] *See, e.g.*, *Rubin v. City Nat'l Bank & Trust Co. of Gloversville*, 131 A.D.2d 150, 152 (3d Dep't 1987) (citing Webster's Third New International Dictionary to interpret the "ordinary usage and dictionary definition" of the word "any," which was defined as "one indifferently out of more than two; one or some indiscriminately of whatever kind") (internal quotation marks omitted); *see also CBS Corp. v. Eaton Corp.*, No. 07-cv-11344, 2009 WL 4756436, at *4 (S.D.N.Y. Dec. 7, 2009) ("[a] sound method for determining the plain meaning of words is to look at their dictionary definitions," referring to the "[c]ontemporary dictionaries" Webster's, American Heritage, and Oxford English; defendant's construction "would unreasonably stretch the plain meaning of the term") (citations omitted).

Recognizing that the meaning of "any" may depend on context to be clarified by factual development, *see Nixon v. Missouri Mun. League*, 541 U.S. 125, 132 (2004), a number of oft-cited dictionaries provide helpful guidance:[16]

- **Cambridge Dictionary** defines "any" as "some, or even the ***smallest*** amount or number of."
- **Oxford English Dictionary** defines "any", including when used as an adjective with a "plural or mass noun"—*i.e.*, "any" before "activities" in the defined term "Commercialize"—as "of whatever sort or kind" (in the context of qualitative force in positive or neutral sense) and "used to refer to a number, however great or ***small***, of (separable things), or a quantity or amount of (a substance, etc.), even the ***smallest***" (in the context of quantitative force).
- **Oxford** similarly defines "any," when being used as an adjective with a "plural or mass noun" and "[i]n interrogative, hypothetical, and conditional contexts," as "used to refer to an unspecified number or quantity of a thing or things, no matter how much or how many; ***some***."
- In relevant part, the **American Heritage Dictionary** defines "any" as "one or some; no matter which," "no matter how much or how ***little***," and "no matter how much or how ***few***; ***some***," and the **Merriam-Webster Dictionary** defines "any" as "***one*** or more—used to indicate an undetermined number or amount."[17]

As these definitions make clear, the plain meaning of "any" prior to a plural noun means "at least one" or "some." It reasonably follows that the parties used "any" before "activities" in the term "Commercialize" to indicate that ***one*** sales or marketing activity, or any possible number of such activities (*i.e.*, ***some***), would be enough to qualify as Commercializing. Even Incyte concedes it can preclude "some activities that fall within the definition of Commercialization." Mot. at 19.[18]

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[16] The dictionaries cited herein are as follows: American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=any; Cambridge Dictionary, https://dictionary.cambridge.org/us/dictionary/english/any; Merriam-Webster Dictionary, https://www merriam-webster.com/dictionary/any; and Oxford English Dictionary, https://www.oed.com/view/Entry/8973?redirectedFrom=any#eid (all last visited May 18, 2020; all emphases added).

[17] While Incyte also cites to this dictionary in the Motion, Incyte curiously omits the exemplar phrases the dictionary uses to equate "any" with "every" and "all," which are in entirely dissimilar contexts. For example, Merriam-Webster notes that "any" could be equated with "every" in the following sentence: "any child would know that."

[18] In contrast, the word "all" is consistently defined by these same dictionaries as the "whole," "total," or "complete" amount or number of the corresponding noun. *See* American Heritage Dictionary, https://ahdictionary.com/word/search html?q=all; Cambridge Dictionary, https://dictionary.cambridge.org/us/ dictionary/english/all; Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/all; Oxford English Dictionary, https://www.oed.com/ view/Entry/5151?redirectedFrom=all#eid (all last visited May 18, 2020); *see also, e.g.*, *Citibank, N.A. v. Jacobsen,* No. 19-cv-959, 2020 WL 772497, at *8 (S.D.N.Y. Feb. 18, 2020) ("The plain meaning of the term 'all,' when modifying a plural noun like 'obligations,' is 'the whole number or sum of' the noun."). "Every" is similarly and consistently defined as amounting to "each" in a full group or "all."

Thus, it is more than plausible to understand that having "Regulatory Exclusivity" means the ability to prevent at least one, or some, marketing and sales activities by competitors with respect to Jakafi. Here, Incyte's ability to bar competition with respect to the treatment of both PV and GVHD (which are major sales drivers) under FDA-issued exclusivities clearly (and certainly plausibly) means that the Licensed Product is "subject to Regulatory Exclusivity."

D. Incyte's Interpretation Impermissibly Relies on Speculation

Based on extrinsic (and disputed) factors well outside the scope of the Complaint, Incyte contends that it cannot "rely on" the orphan drug designations it holds and Jakafi thus should not be deemed "subject to Regulatory Exclusivity" for purposes of the Step Down. *See* Motion at 19. In so doing, Incyte ignores that it obtained exclusivities for treating PV and GVHD for a reason, and even did so well after the now-expired designation for MF had been approved. Incyte also ignores what holding these designations means as a matter of continuing sales success and in relation to competition (for which there is still none) in the relevant market.

While it is debatable whether the Court can take judicial notice of the IQVIA Institute report cited by Incyte, *see* Motion at 19, even that report clearly articulates that drugs awarded "multiple orphan designations that end at different times" will "experience some level of market exclusivity for a period well in excess of seven years." IQVIA Institute for Human Data Science, Orphan Drugs in the United States (Dec. 2018) (as cited in Motion) at 9. That is, any generic competition (which does not yet exist) could only occur with respect to treating MF and Incyte would still retain meaningful legal protections with respect to the treatment of PV and GVHD. At present, Incyte retains the entire ruxolitinib market in the U.S., and even if a generic manufacturer was to compete (and there is no indication that there is even one on the horizon), Incyte will retain the ability to exclude it from partaking in sales and marketing of ruxolitinib for the treatment of both PV and GVHD (*i.e.*, Commercializing Jakafi). *See* Compl. ¶¶ 19-20; Mot. at 19.

Incyte resorts to describing hypothetical "skinny" or "carve-out" labeling that a now non-existent competitor may or may not pursue, as well as hypothetical scenarios whereby a physician may prescribe generic ruxolitinib off-label. *See* Mot. at 21-23. But pure speculation about scenarios outside the pleading as to what competitors or doctors prospectively may do, let alone what impact it possibly could have on sales, provides no viable ground to challenge the sufficiency of Novartis' pleading of a plausible contract interpretation. Indeed, Incyte concedes ongoing "patent protections," Mot. at 22 n.11, which allows it to both delay and challenge any generic competitor's request for FDA approval.[19] Incyte's suggestion that the expiration of the MF designation has "serious potential consequences," *id.*, thus leaps to the far-fetched scenario in which a potential generic competitor successfully challenges the validity of Incyte's patents and receives FDA approval to compete. Speculation about improbable scenarios is disfavored for contract interpretation, and certainly does not satisfy Incyte's burden on its Motion.

In addition, the cases that Incyte cites for "skinny" or "carve-out" labeling, *see* Mot. at 21, have no bearing here (except to highlight the impermissibility of Incyte's arguments), as none of them concern a motion to dismiss, let alone basing such a motion on extrinsic matters. Further, all of them involve, unlike here, actual generic presence in the relevant market, which is not the case with Jakafi. The case Incyte cites for the potential for "off-label prescribing" is similarly inapplicable on the Motion as it concerns a challenge to FDA regulations (and is not a commercial dispute). *See* Mot. at 23. By relying on what hypothetical actors may seek to do with respect to labeling or prescribing, Incyte in fact "all but concedes" the infirmity of its Motion by referencing "extra-contractual" matters. *Columbia Cas. Co.*, 2015 WL 3999192, at *8.

[19] FDA, Patent Certifications and Suitability Petitions, *available at* https://www fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions (last visited May 18, 2020) (discussing paragraph IV patent certification for generic manufacturer seeking FDA approval and 30-month stay during any patent challenge).

III. COMMERCIAL LOGIC CONFIRMS NOVARTIS' INTERPRETATION IS NOT ONLY PLAUSIBLE BUT COMPELLING

Beyond the Agreement itself, what Incyte calls "commercial absurdity," Mot. at 5, actually only serves to confirm Novartis' interpretation (and certainly its plausibility). As set forth in Section 8.3(c), the parties agreed to share in the economic success of any drug they jointly developed and Commercialized, irrespective of the country of sale. To that end, full royalties are due while the Licensed Product enjoys a strong market position, and unless and until there is a deterioration in the value of the Licensed Product, which, in turn, justifies invocation of the Step Down. While the second scenario in the Step Down (tied to Generic Competition) is triggered by actual, meaningful competition with the Licensed Product, the first scenario (tied to an absence of patent or exclusivity) similarly reflects a deterioration in value, as no competitor is attracted to competing in the market even though barriers do not prevent entry.

Tested against the structure of Section 8.3(c), the extraordinary illogic of Incyte's position is that it would impose the Step Down even though the Licensed Product, Jakafi, has not suffered any market deterioration whatsoever. Critically, nothing negative has transpired with respect to the Licensed Product's sales in the U.S. between the quarter that Incyte was paying full royalties (Q4 2018) and the quarter when it sought to invoke the Step Down (Q1 2019). Nor has anything negative transpired since the first quarter of last year. To the contrary, sales of the Licensed Product have steadily and substantially **increased**, and are expected to continue to do so. It defies reason and the express structure of the Step Down to impose a 50% royalty reduction clearly geared to market deterioration when the market position of the Licensed Product here is as sound as ever and only growing. It also would lead to an unjustifiable windfall for Incyte, as it would benefit from robust, indeed increasing, sales, while its counter-party in the collaboration would see its share of the benefits cut in half for no explicable business or economic reason. *See, e.g.*, *Cole v.*

Macklowe, 99 A.D.3d 595, 596 (1st Dep't 2012) (finding defendants' view "represents a windfall to the defendants that is absurd, not commercially reasonable and contrary to the express terms of the agreement"); *Homeward Residential, Inc. v. Sand Canyon Corp.*, No. 13-cv-2107, 2014 WL 2510809, at *9-10 (S.D.N.Y. May 28, 2014) (denying motion to dismiss contract claims where defendant's interpretation is "commercially unreasonable, or contrary to the reasonable expectations of the parties" and "common sense may tilt in favor of Plaintiff's interpretation").

Recognizing as much, Incyte resorts to a truly nonsensical argument that Novartis' contract interpretation would omit any incentive for Incyte to seek additional patent protection or regulatory exclusivities because then Incyte would need to share the benefits of doing so with Novartis. *See* Mot. at 6. But sharing in the benefits of Commercialization is exactly what the parties' collaboration is all about. This is particularly so, since Novartis has been materially contributing to the Commercialization of ruxolitinib in the U.S. since the Agreement was signed in 2009.

Indeed, Incyte's claim of some disincentive or "penalty" is also belied by the fact that, even with a full royalty rate in effect, Incyte will still retain **at least 95%** of the annual Net Sales of Jakafi, as Novartis' position involves applying the 5% full royalty rate in lieu of 2.5% under the Step Down. Given that the rate differential is 2.5%, there is no indicia anywhere that continuation of the full royalty rate, without any Step Down, would disincentive Incyte—which will gain the lion's share of benefits in all events—from efforts to grow and extend Jakafi's market position in the U.S. Thus, the clear weight of commercial logic provides further grounds for finding that Novartis' contract interpretation is not just plausible, but, in fact, compelling and justifies denial of the Motion and proceeding with the case.

CONCLUSION

For all these reasons, the Motion should be denied. To the extent, however, the Court finds any pleading deficiency, Novartis requests leave to replead in an Amended Complaint.

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Respectfully Submitted,

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